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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/765,725 | 01/26/2004 | Michael J. Drews | ARB-9014 | 2546 |
| 23410 7590 03/06/2009 Vista IP Law Group LLP 2040 MAIN STREET, 9TH FLOOR IRVINE, CA 92614 | | | | |
| EXAMINER PELLEGRINO, BRIAN E | | | | |
| ART UNIT 3738 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,725

Applicant(s)

DREWS ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 36-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41, 44, 45, 47-49, 52-55, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 42, 43, 50, 51, 56 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II in the reply filed on 11/19/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-22,45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 36,44,46,49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrowsky et al. (3628535) in view of Lane (6371983). Ostrowsky et al. show (Fig. 2) a heart valve assembly with a base member (40) having a generally annular shaped body and a plurality of elongate guide members (18) extending upward beyond and away from the base. Fig. 1 shows the guide members are receivable through a valve member (28,30) that is formed as an annular frame. It is also noted that the assembly includes a flexible cuff **20** that extends *around a periphery* of the body. The Examiner interprets "around a periphery" to be in close proximity. However, Ostrowsky et al. fail to

disclose the valve member to be multi-lobular shape. Lane teaches (Figs. 1,8) that a valve member is multi-lobular in shape to reduce stresses during opening and closing, col. 2, lines 3-5. It would have been obvious to one of ordinary skill in the art to use a multi-lobular structure as taught by Lane with the valve assembly of Ostrowsky et al. such that it lowers stress in the opening and closing of the valve. Regarding claim 44, it can be seen that the ends **22** of the guide members extend through the valve member and there is a plurality and thus there is a plurality of guide channels. With respect to claim 46, the channels can be considered as recesses since they form openings in the valve member. Since the guides extend through base member (40) it can be interpreted they are detachable from the base member.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrowsky et al. '535 in view of Lane '983 as applied to claim 36 above, and further in view of Schreck (6454799). Ostrowsky et al. in view of Lane is explained above. However, Ostrowsky et al. as modified by Lane fail to disclose the guide members are rectangular in cross-section. Schreck teaches (Fig. 2) elongate guide members **72** for a valve member that are rectangular in cross-section and provide a greater cross-section to prevent unwanted detachment, col. 7, lines 54-57. It would have been obvious to one of ordinary skill in the art to use rectangular cross-sectional guides as taught by Schreck with the valve device of Ostrowsky et al. in view of Lane since such a modification (change in shape cross-section) only involves routine skill in the art and would have predictable results of better structural stability.

Claims 37-41, 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrowsky et al. in view of Lane as applied to claim 36 above, and further in view of Bicer (5061278). Ostrowsky et al. in view of Lane is explained supra. However, Ostrowsky as modified by Lane fail to explicitly disclose a leaflet valve is advantageously used. Bicer teaches that leaflet valves are advantageously used instead of ball valves, col. 2, lines 40-45. It would have been obvious to one of ordinary skill in the art to use a valve member with leaflets per the teaching of Bicer with the guide assembly of Ostrowsky as modified by Lane since it reduces pressure differentials. In substituting a leaflet valve device as Lane's with the guide assembly of Ostrowsky per the teaching of Bicer it would include a flexible cuff as taught by Lane, which teaches a base member **25** having a generally annular shaped body and a flexible cuff **17** extending around the periphery. Regarding claim 41, Lane also teaches cooperating connectors for securing a valve member to a base, Fig. 4 shows the elongate pins and complementary connectors in the form of apertures.

Claims 58,59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrowsky et al. in view of Lane and Bicer as applied to claim 52 above, and further in view of Gross (5662704). Ostrowsky et al. as modified in view of Lane per Bicer's teaching is explained above. However, Ostrowsky in view of Lane per Bicer's teaching fail to disclose additional guides or markers. Gross teaches that additional "guides" or markers are used on a prosthetic valve apparatus, col. 5, lines 1-7. It would have been obvious to one of ordinary skill in the art to use markers as taught by Gross such that the proper alignment or connection of components can be accomplished with the valve

apparatus of Ostrowsky et al. as modified by Lane per Bicer such that the device can be properly positioned and operate appropriately.

Allowable Subject Matter

Claims 42,43,50,51,56,57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 36, 52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738